



U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2

March 29, 2019

BY ELECTRONIC MAIL

Jay Nickerson
Bureau of Case Management,
Site Remediation and Waste Management Program, NJDEP
Mail Code 401-05F
P.O. Box 420
Trenton, NJ 08625-0420

Jay,

The EPA has reviewed the New Jersey Department of Environmental Protection's March 13, 2019 email (Hayton to Salkie, subject: LPRSA – NJDEP preliminary comments: Oct 2018 BERA), and the attached document: "*Lower Passaic River Baseline Ecological Risk Assessment, Oct. 2018: NJDEP preliminary review comments, March 13, 2019*". The main points of the comment letter are addressed below:

GENERAL COMMENTS

NJDEP comment: "*The use of dual TRVs is precedent-setting and EPA must realize the strain it will place on SRWMP resources if the BERA is posted on the website and this approach is adopted by LSRPs.*"

EPA response: The use of two sets of TRVs on the LPRSA 17-Mile BERA is not precedent-setting. Alternative TRVs, derived by PRPs in addition to the EPA-provided TRVs, have been used at the Newtown Creek Site (EPA Region 2), the Upper Columbia River Site (EPA Region 10 – draft BERA) and at the Kalamazoo River Site (EPA Region 5 – draft BERA). The strain placed on SRWMP resources is the same strain placed on EPA resources, as EPA will also verify all of the alternative TRVs. We are hopeful that the potential future strain on NJDEP resources should be lessened by the inclusion of the NJDEP statement within the LPRSA 17-Mile BERA, which will likely indicate that "use of multiple sets of TRVs is not supported by NJDEP policy." This will highlight for LSRPs working on sites under New Jersey cleanup authorities that NJDEP will not approve the use of multiple sets of TRVs on NJDEP projects. EPA guidance permits PRPs to submit alternative TRVs for use in ecological risk assessments. In preparing these responses, EPA reviewed NJDEP guidance to assess how different the approach

used by NJDEP is from the EPA process. Upon review, it appears that the NJDEP guidance allows for PRPs to also submit TRV information.

NJDEP comment: *“NJDEP’s Ecological Evaluation Technical Guidance (EETG), used by hundreds of LSRP for thousands of New Jersey sites with potential ecological impact, does not advocate the use of more than one set of TRVs.”*

EPA response: A quick review of the NJDEP EERG showed that the EETG does not advocate the use of more than one set of TRVs, but neither does it preclude the use of more than one set of TRVs. Section [6.1.3.3](#) of the EETG, on Selection of Toxicity Reference Values states, “...provides the user with a framework from which to develop TRVs; however, as with all guidance documents issued by the NJDEP, the person conducting the remediation may deviate from this approach and propose an alternative TRV based on site-specific circumstances provided that adequate justification is provided.” EPA’s agreement to allow the CPG to submit TRVs for the LPRA 17-Mile BERA appears to be consistent with this approach.

NJDEP comment: *“The LSRP program was established to expedite the RI process and we are not afforded the time or resources to go through a months-long process to develop mutually-agreeable multiple sets of TRVs...NJDEP has thousands of contaminated sites in SRWMP that potentially require an ERA, and this dual TRV approach, if used as a model for LSRPs state-wide, would put an undue strain on the Department’s technical resources and staff.”*

EPA response: EPA acknowledges NJDEP’s concerns, but the use of multiple sets of TRVs is not inconsistent with EPA guidance and as noted above the potential for future strain on NJDEP resources should be lessened by the inclusion of the NJDEP statement within the LPRSA 17-Mile BERA, which will likely indicate that “use of multiple sets of TRVs is not supported by NJDEP policy”.

SPECIFIC COMMENTS

NJDEP comment: *“1. (p. 497) – Section 8 Bird Assessment – In introductory text and elsewhere in this section, for contaminants where HQs ≥ 1 , the term “preliminary” COCs is used...”*

EPA response: The term “preliminary COCs” is defined in the LPRSA 17-Mile BERA as follows: “Preliminary COC were identified as those COPECs with HQs ≥ 1.0 based on any line of evidence (LOE) and effect-level concentration (i.e. HQ ≥ 1.0 based on a range of lowest-observed-adverse-effect levels [LOAELs] for tissue and diet LOEs, HQ ≥ 1.0 based on acute or chronic surface water TRVs; HQ ≥ 1.0 based on plant-specific sediment TRVs).”

The use of the term “preliminary” originated from a discussion between EPA and the CPG about including COCs and risk drivers in the BERA. The CPG wanted to include a separate section where COCs and PRGs were derived. EPA indicated that the BERA is not the correct place for this kind of analysis, as COCs and PRGs should be identified in the FS and memorialized in the ROD. Thus, the term “preliminary COC” was developed

to distinguish between compounds that were carried from the SLERA to the BERA (i.e., COPECs) and those that were identified in the BERA as needing to be carried forward to the FS (i.e., preliminary COCs). The LPRSA 17-Mile BERA states that “preliminary COCs” will be further evaluated in the FS.

NJDEP comment: “2. (pp. 517) Section [8.1.3.1](#) *Methods for selecting TRVs – Two sets of bird dietary toxicity reference values (TRVs) continued to be used for the derivation of HQs...*”

EPA response: See the response to the three general comments above.

NJDEP comment: Specific comment 2, first bullet: “...Further, SRWMP believes that the most conservative NOAEL-LOAEL TRV set based on the verified studies and approaches from “EPA’s Review of CPG’s alternative TRVs” (Excel spreadsheet dated 12/22/17) should be selected to protect sensitive species and endpoints, an this should be stated prominently in the BERA...”

EPA response: EPA will consider both sets of TRVs when developing risk-based preliminary remedial goals (PRGs). A brief outline of the process is discussed in EPA’s “LPRSA 17-Mile BERA Action Item Responses”

NJDEP comment: Specific comment 2, second bullet: “The risk characterization step of the BERA should provide an unequivocal determination of elevated risk via HQ determinations, however results from the use of dual TRV sets precludes accomplishment of this objective...Both results cannot be correct and there is no written indication how this issue will be managed post-BERA.”

EPA response: EPA will consider both sets of TRVs when developing risk-based remedial goals. Any chemical with an HQ that exceeds acceptable levels will be included in the list of chemicals for which PRGs are developed.

NJDEP comment: Specific comment 2, third bullet: “...Other than perhaps Newtown Creek (same consultant), can the EPA provide NJDEP citations where this approach has been used?”

EPA response: The Kalamazoo River Area 4 Supplemental Remedial Investigation (SRI) includes a BERA in which two sets of TRVs were used. EPA Region 5 is in the process of finalizing the document. The Upper Columbia River Site includes a draft BERA in which two sets of TRVs were used, but that document has not been finalized by EPA Region 10. We have discussed the use of multiple sets of TRVs with personnel in the EPA HQ Office of Superfund Remediation and Technology Innovation (OSRTI), who indicated that the use of multiple TRVs is acceptable as it is not inconsistent with EPA guidance.

NJDEP comment: Specific comment 2, fourth bullet: “...Two sets of toxicity data were not used in the LPRSA Human Health Risk Assessment (HHRA)... While there is not one standard TRV database analogous to IRIS for ecological toxicity data, the TRVs in the 2014 FFS were peer-

reviewed by USEPA, Battelle, NOAA, USFWS, and NJDEP, and those single sets (or more conservative sets) should be used for those contaminants in this revised BERA.”

EPA response: As NJDEP is aware, the human health risk assessment process is more prescriptive than the ecological risk assessment process. Unlike the human health risk assessment process, there is no national database for ecological screening TRVs. EPA BERA guidance allows for the use of alternative TRVs. The TRVs from the 2014 FFS (and the Lower 8.3-Mile BERA) were included in the LPRSA 17-Mile BERA.

NJDEP comment: Specific comment 2, fifth bullet: *“To compare HQs between the lower 8 and upper 9 miles of the river, SRWMP believes that TRVs in the denominator should be held constant, such that differences in risk can be attributed to differences in sediment and tissue concentrations (i.e., exposure variables in numerator.”*

EPA response: The TRVs that were used in the Lower 8.3-Mile BERA were also used in the LPRSA 17-Mile BERA and in the Upper 9-Mile BERA. In addition, a set of alternative TRVs was included. Additionally, there are differences between the lower 8.3 miles and the upper 9 miles. The upper 9 miles of the LPRSA is primarily a freshwater environment, while the lower 8.3 miles is primarily an estuarine environment, so the exposures are not identical.

NJDEP comment: Specific comment “3. (p. 519-522) Section [8.1.3.2](#) Selected TRVs for birds and Table 8-11 Bird dietary TRVs. Total PAHs – Please explain why in “EPA’s Review of CPG’s alternative TRVs” (Excel spreadsheet dated 6/8/17) the NOAEL TRV of 40,000 ug/kg bw/day was rejected but was accepted in the 12/22/17 spreadsheet.”

EPA response: The 40,000 ug/kg TRV was not initially acceptable to EPA because it did not include more sensitive endpoints (loss/recovery of body weight, and increase in liver weight), but after review of the survival, growth, and reproduction endpoints (which are the primary endpoints for TRV derivation), EPA verified the TRV as having been selected appropriately from the cited paper.

NJDEP comment: Specific comment “3. (p. 519-522) Section [8.1.3.2](#) Selected TRVs for birds and Table 8-11 Bird dietary TRVs. PCDD/PCDF TEQ – the basis for both the FFS-based and CPG-based bird TRV for PDCC/PCDF TEQ is Nosek et al. (1992), derived for the ring-necked pheasant. In the 2014 FFS...the NOAEL and LOAEL were divided by an interspecies factor of five to account for species that are more sensitive than the selected surrogate receptors; CPG did not apply this factor, resulting in the CPG-based TRVs in Table 8-11 that are 5X higher than those based on the FFS...”

EPA response: The interspecies factor is sometimes used, based on professional judgement, when deriving TRVs. EPA chose to include an interspecies factor of 5 for the derivation of the FFS value, while the CPG used the same study without an interspecies factor of 5. The EPA values resulted in an upper-bound HQ risk of 21 and the use of CPG values resulted in an upper-bound HQ risk of 4.2, with both analyses identifying PCDD/PCDF TEQ as a COC for dietary dose in avian species.

NJDEP comment: Specific comment “4. (p. 529) Section 8.1.4 Risk Characterization...For the spotted sandpiper and great blue heron, the dietary assessment was limited to mudflat area exposure, therefore, for both species, please provide a figure that indicates NOAEL and LOAEL HQs in individual mudflats.”

EPA response: The LPRSA 17-Mile BERA did not break down NOAEL and LOAEL HQs for each individual mudflat, as risk was assessed for the 17-Mile and Upper 9-Mile sections of the river.

NJDEP comment: Specific comment “5. (p. 533) Section 8.1.4 Risk Characterization...NOAEL-based HQs should be addressed...”

EPA response: The discussion of NOAEL/LOAEL will be addressed during preparation of the LPRSA 17-Mile BERA and BHHRA, when PRGs are developed. While relying on just the NOAEL would not really be appropriate for an urban river, relying only on the LOAEL is also not appropriate. As discussed above, EPA will consider both sets of TRVs when developing risk-based PRGs. A brief outline of the process is discussed in EPA’s “LPRSA 17-Mile BERA Action Item Responses.”

If there are any questions or clarifications needed, please contact me to discuss.

Sincerely,

A handwritten signature in dark ink, appearing to read "Diane Salkie", written in a cursive style.

Diane Salkie, Remedial Project Manager
Lower Passaic River Study Area RI/FS